UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

UNITED STATES' OPPOSITION TO THE ROXANE DEFENDANTS' MOTION FOR A FINDING OF SPOLIATION AND FOR SANCTIONS

Joining Abbott Laboratories (Abbott) and Dey, Inc. (Dey), who previously filed motions asking the Court to find that the United States failed to preserve purportedly "critical" evidence, Roxane has filed its own Motion for a Finding of Spoliation of Evidence And for Sanctions (M.D. # 6254, Sub. # 274), claiming that Roxane was "particularly prejudiced" by the alleged failure to preserve two kinds of evidence: "pricing data pertaining to the Medicare Durable Medical Equipment Regional Carriers' (the "DMERCs") classification of Roxane drugs as generics or brands"; and "actual State Medicaid claims data." Roxane's argument as to evidence of the DMERCs' purported "misclassification" of Roxane's drugs fails. The specific evidence Roxane claims was spoliated – the so-called "Redbook CDs" – was never requested by Roxane in discovery, still exists, and is irrelevant in any event because the DMERCs *correctly* classified NovaPlus® ipratropium bromide as a brand according to criteria published in the Federal Register.

As set forth more fully below, although Roxane served several discovery requests related to the DMERCs, its request(s) did not encompass the information that Roxane now claims has "largely vanished or been destroyed:" that is, the "electronic database provided by the Redbook pricing compendia on quarterly CD-roms" purportedly containing "underlying data" that Roxane claims the DMERCs relied upon in classifying Roxane's NovaPlus® ipratropium bromide as either a generic or brand product. Roxane Defendants' Memorandum in Support of Their Motion for a Finding of Spoliation of Evidence and For Sanctions (Rox. Mem.) at 1-2, 4. Even if its requests arguably could be read to encompass such information, Roxane knew the United States did not produce the pricing data at issue, yet Roxane did not press for this information at any time during the discovery period or, indeed, at any time prior to filing the instant motion. Roxane could have purchased the data from Red Book but did not. Also, the United States has since learned that two DMERCs collectively still have all but one of the quarterly Red Book CD-ROMs used during the period when one or more of the DMERCs included the NovaPlus® products in their arrays (14 CDs covering 2000 Q2 through 2003 Q4), and the United States is in the process of producing these CDs to Roxane.[1]

In any event, evidence of the specific information available to or used by the DMERCs in classifying drugs is immaterial to any defense Roxane might have because the DMERCs' classification was correct according to a 1998 final rule published in the Federal Register. Documents showing that three of the four DMERCs classified NovaPlus® as a brand were

[1] The United States believes that Roxane did not properly request this information, and that its current motion is, in effect, a belated discovery request. Nonetheless, in the interests of full disclosure, the United States will produce the relevant Red Book CD ROMs once it obtains the necessary permission from Red Book's owner, Thompson Reuters.

produced to Roxane in January and March 2008. The relevant evidence, therefore, was timely produced.

With regard to Roxane's argument that state-level Medicaid claims data was spoliated, Roxane has made no showing of spoliation, and its position is belied by this Court's prior recognition that the United States had no duty to produce such data and that Roxane was free to subpoena it directly from the States. Furthermore, the United States was under no obligation to require sovereign States to preserve data in their possession, custody, and control.

I. BACKGROUND

The United States filed its Complaint in this case on February 9, 2007. The Complaint identified the Healthcare Common Procedural Coding System ("HCPCS") codes used by Medicare to reimburse for ipratropium bromide (J7645, K0518, and J7644). Complaint, ¶ 42. The Complaint also put Roxane on notice that DMERCs processed and paid Medicare claims on behalf of CMS, and that from 1999 through 2003, Medicare reimbursement was based on the lower of 95% of the median of published generic AWPs or the AWP of the least expensive brand name drug. *Id.*, ¶¶ 36-37, 55. In April 2007, as part of the United States' initial disclosures, the United States produced array documents for ipratropium bromide showing that DMERCs relied on Red Book, including a "Redbook Database," for AWP data. *See, e.g.*, Exhibits 1 and 6 to the Declaration of George B. Henderson, II, Submitting Exhibits In Opposition to the Roxane Defendants' Motion for a Finding of Spoliation and for Sanctions ("Henderson Decl."), filed herewith. The arrays also showed that at least some of the DMERCs treated Roxane's NovaPlus® products as brand drugs. *Id.* Additional arrays were produced on September 26, 2007. Henderson Decl., Exhibits 3 and 7.

Roxane served its only set of document requests on November 7, 2007. The United States responded to these requests on December 7, 2007, and, as it already had been doing for months prior to receiving Roxane's requests, continued to produce documents to Roxane throughout the discovery period. The only request that even arguably could have encompassed the Redbook CDs at issue here was Request Number 4, which sought "all documents relating to how DMERCs or Medicare Carriers determined the payment amount for the Subject Drugs." In December 2007, and January and March 2008, the United States produced additional DMERC pricing arrays for the ipratropium bromide HCPCS codes to Roxane. See Henderson Decl., Exhibits 2-5, and 7-10. Those arrays showed that the DMERCs included Roxane's NovaPlus® ipratropium bromide among the products considered in setting reimbursement for ipratropium bromide, and that three of the four DMERCs treated NovaPlus® ipratropium bromide as a "brand." The arrays also showed that the DMERCs used the Red Book, including the "Red Book Database" or the "Red Book Quarterly CD" as the source of the AWPs relied upon to determine the allowable amounts.

Roxane deposed corporate representatives of two of the DMERCs in February and March 2008, and a representative of a third DMERC for several days in August and September 2008. Testimony at these depositions confirmed that the DMERCs used the Red Book to obtain AWPs, and indicated that at least one of the DMERCs consulted the Red Book in determining whether products were brands or generics. The testimony further indicated that the DMERCs used the printed version of the Red Book prior to 1999, and switched to electronic CD-ROM updates to

the Red Book thereafter.[2] DMERC witnesses testified that the electronic CD-ROM updates were programmed to become inaccessible after a new CD-ROM was loaded. An employee at one DMERC, however, had a practice of printing out pages from the CD-ROM whenever there were changes in reported prices. Such hard copy printouts were produced to Roxane.

Roxane's document requests to the United States did not seek production of any Red Book pricing data, such as the printed versions of the Red Book utilized by the DMERCs prior to 1999, or the electronic CD-ROM updates to the Red Book utilized from 1999 - 2003.[3] The United States did not understand Request Number 4 to seek proprietary electronic Red Book databases, and Roxane never explained to the United States that Request Number 4 (or any other request) was meant to include the Red Book CDs. Consequently, no such data was produced.[4] Roxane was aware that the United States did not produce such data. During the discovery period, however, Roxane did not address the issue in any follow up correspondence, nor in any of the several Local Rule 7.1 conferences held between counsel for Roxane and the United States, nor in a motion to compel, although Roxane filed at least one such motion.

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[2] The evidence establishes that one DMERC – AdminaStar – consulted the Red Book in determining whether NovaPlus® ipratropium bromide was a brand or generic product. The CIGNA and Palmetto DMERCs classified NovaPlus® ipratropium bromide based on whether the product had a product name other than the generic chemical name of the drug.

[3] As commercial products sold by Red Book, such information was presumably available for Roxane to purchase. In fact, counsel for the United States understands, based on communications with counsel for Thompson Reuters, that the electronic Red Book data for 2000 forward is available for purchase from Red Book. Apparently Roxane has made no effort to acquire the data in this fashion.

[4] The reproduction of such data is restricted according to licensing agreements between the DMERCs and Red Book.

At a March 13, 2008, deposition, Carolyn Helton (a corporate representative of the CIGNA DMERC) testified that the Red Book data used by CIGNA had not been produced in discovery. Counsel for Roxane requested at the deposition that the Red Book materials be produced; however, counsel for the United States stated that he doubted that the United States would do so. Henderson Decl., Exhibit 11. Roxane never followed up on the request and never consulted with government counsel on the issue prior to filing the instant motion. The United States has learned that two DMERCs collectively retained copies of all but one of the electronic CD-ROM updates to the Red Book utilized during the period when NovaPlus® products appeared in the arrays, 2000 Q2 through 2003 Q4. The United States is in the process of producing these CDs (plus some earlier ones) to Roxane.

II. ARGUMENT

A. The Red Book Data Roxane Claims Was Spoliated Was Not Requested in Discovery and Still Exists

As detailed above, two DMERC retained the electronic CD-ROM updates to the Red Books utilized during the period at issue. These constitute 14 CD-ROMs, which the United States is in the process of producing to Roxane. The United States did not previously produce these CDs because they were never the subject of a proper discovery request. The only discovery request which even arguably could include the information at issue is Roxane's document request number 4, which sought "all documents relating to how DMERCs or Medicare Carriers determined the payment amount for the Subject Drugs." It strains credulity to suggest that Roxane meant, and expected the United States to understand, that the commercial pricing

databases utilized by the DMERCs were documents "relating to *how* [the DMERCs] determined the payment amount" and therefore were encompassed by Roxane's Request Number 4.[5]

Moreover, despite Roxane's obvious awareness of the data and that it had not been produced, and despite numerous conferences and discussions regarding the parties' respective document productions in this case, Roxane did not request that the United States produce the Red Book CD-ROM updates, except for a single half-hearted oral request at a March 2008 deposition. Believing that the information contained on the CD-ROMs was irrelevant (*see* Section B *infra*) and commercially available, counsel for the United States said he "doubted" the United States would produce the information. In the remaining eight months of fact discovery Roxane never followed up with a letter request, formal written document request, or motion to compel.

It is evident that where documents, never properly requested in discovery, still exist, there cannot be a finding of spoliation of evidence. Roxane's motion, therefore, should be denied.

B. The Red Book Data Roxane Claims Was Spoliated Is Irrelevant to this Litigation

Although Roxane claims the Red Book electronic data is "undeniably of critical importance to Roxane's defenses," Rox. Mem. at 2, in fact the information has *no* relevance, since the DMERCs did not "misclassify" Roxane's NovaPlus® drugs. Roxane's argument that it has been "severely prejudiced" by the United States' purported failure to produce the Red Book CD-ROM updates is therefore wrong, because it is entirely premised on the mistaken assumption that the DMERCs' classification of NovaPlus® ipratropium bromide as a brand was an error. As

[5] In general, the parties to the United States' suits against Abbott, Dey, and Roxane, have declined to produce to one another electronic data commercially available from vendors such as IMS, First DataBank, and Red Book.

detailed at pages 25-31 of the United States' Consolidated Memorandum of Law (M.D.# 6291, Sub.# 298-3), the classification of NovaPlus® ipratropium bromide was in accord with CMS' published rules, which define a brand product as a product that is "marketed under a labeled name that is other than the generic chemical name of the drug or biological." 63 Fed. Reg. 58,814, 58,849 (Nov. 2, 1998). CMS specifically considered and rejected a definition of "brand" that was limited to the product of the innovator company:

> Our definition of "brand" is any product that is marketed under a name other than the generic chemical name of the drug. If a manufacturer chooses to market its product under a proprietary name rather than the generic chemical name of the drug, we believe this is a brand. We do not limit the definition of "brand" to the innovator company product or any product manufactured under a direct license from the innovator.

Id. The evidence plainly establishes that NovaPlus® is a proprietary name, and Roxane's promotion of NovaPlus® ipratropium bromide consistently identified the product as part of the NovaPlus® brand. Acting pursuant to CMS' published guidance, three of the four DMERCs *correctly* treated NovaPlus® ipratropium bromide as a brand. Since the classification was appropriate, further discovery of exactly how or why one particular DMERCs classified NovaPlus® products as it did – including evidence of how NovaPlus® ipratropium bromide was identified in the Red Book CD-ROMs – is simply irrelevant.

C. There Is No Merit to Roxane's Assertion That State Claims Data In the Possession, Custody, and Control of State Medicaid Agencies Has Been Spoliated

Roxane argues that the United States violated an obligation preserve State Medicaid claims data of individual States and that the United States should therefore be precluded from recovering damages with regard to all time periods and States for which such data has not been

produced. Roxane's argument is without merit, and, in reality is but a re-casting of argument previously made and rejected by this Court.

To begin with, Roxane incorrectly presumes that whatever state-level claims data[6] the United States did not produce in discovery has been spoliated. But, as previously stated to the Court and parties, the United States has never undertaken any obligation to collect all available state-level Medicaid claims data. At the November 13, 2008, scheduling conference, counsel for Roxane argued that the United States was required to produce all such state-level claims data, and that a failure to do so meant that all related damages claims must be dropped. *See* Henderson Decl., Ex. 12, Transcript of November 13, 2008, at pp. 33-34. Counsel for the government explained that there existed state-level claims data of numerous states that the United States did not collect and did not have. *Id*. at 34-34. Counsel for the government further explained, "I think probably every state has claims data. They process claims. We have not had, quite frankly, the resources to go out and -- it's very time-consuming to collect this data, so we have not done it for all fifty states, and some states simply haven't produced it to us. So we just don't have it all, and we're unlikely to get much more." *Id*. at pp. 44-45.[7] The Court ruled that,

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[6] By "state-level claims data," the United States means the Medicaid claims data generated by a state in its day-to-day processing of pharmacy claims for reimbursement to its Medicaid program, as distinct from data obtained by CMS from States pursuant to CMS's oversight responsibilities. The former data generally includes more data fields than does the latter data. The United States understands Roxane to be addressing only the state-level claims data.

[7] *See also* United States' Memorandum in Opposition To Dey's Motion to Extend the Production Deadline For the Limited Purpose of Receiving Medicaid Claims Data (M.D. #5800, Sub. #132). As the Court might well understand, the United States made no effort to obtain state-level data from some States, and relied on voluntary efforts as to other States. Some States simply declined to devote resources to produce data. In some instances, historic claims data was

(continued...)

if the defendants wanted all such data, they could subpoena it from the States. *Id*. at 45 ("I tell you what, if you want to subpoena it, subpoena it."). The Court further ruled that questions about whether the United States could recover damages for States and time periods for which it did not have state-level claims data should be addressed in summary judgment proceedings. *Id*. at 35-36. Implicit in the Court's ruling was the recognition that the United States had no obligation to produce state-level data that the United States did not possess because such data was not within its possession, custody, or control.

Roxane now takes the extreme position of seeking, in essence, a ruling that data in the possession of other sovereigns, which the United States was under no obligation to collect and produce, which the United States did not collect, and which Roxane itself could have subpoenaed but did not, is, by virtue of the United States' asserted failure to produce, presumed to have been spoliated. Roxane's illogical view and the sanction it seeks are flatly inconsistent with the Court's prior rulings and should be rejected. Roxane has made no showing regarding what, if any, pertinent state-level data was destroyed, but instead simply rests on the specious presumption that if the government did not produce it, it must have been spoliated.

Roxane cites to no authority for the proposition that the United States had a duty to preserve information in the possession, custody, and control of third parties. The United States is aware of none. Rather, in the present circumstances, the scope of the duty to preserve evidence should be coextensive with the scope of the duty to produce documents, i.e., it is limited to documents in the possession, custody, or control of the party. To conclude otherwise would

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[7](...continued)
archived in obsolete data systems and could not be retrieved without unreasonable time and effort.

potentially extend the duty to require preservation of evidence in the possession, custody, and control of all variety of third parties – independent contractors, customers, or mere third party witnesses. Courts have not recognized any such radical expansion of the duty to preserve. *See Townsend v. American Insulated Panel Co.*, 174 F.R.D. 1, 5 (D. Mass. 1997) (Collings, M.J.) ("the duty [to preserve evidence] does not extend to evidence which is not in the litigant's possession or custody and over which the litigant has no control"); *Friends for All Children, Inc. v. Lockheed Aircraft Corp*., 587 F. Supp. 180, 189 (D. D.C.), *modified on reconsideration*, 593 F. Supp. 388 (D. D.C.), *aff'd*, 746 F.2d 816 (D.C. Cir. 1984); Jamie S. Gorelick, *et al.*, *Destruction of Evidence* (1989) § 210 ("destruction of evidence by third parties does not give rise to the inference [of spoliation]") & Supp. 2009 (collecting cases).[8] In the present case, there is no suggestion or indication that the United States was aware of or in any way responsible for any loss or destruction of data or documents in the possession, custody, and control of State agencies. Therefore, no finding of spoliation is appropriate here.

Finally, Roxane has made no showing of prejudice, instead relying solely on rhetoric. As indicated above, the Court expressly advised Roxane that it could subpoena the State claims data, but Roxane did not. Roxane should not be heard to complain now about the United States' failure to subpoena it. *Cf. Fujutsu Limited v. Federal Express Corp.*, 247 F.3d 423, 435-436 (2nd Cir. 2001) (affirming district court's refusal to impose sanction for defendant's disposal of evidence where plaintiff never asked to inspect the evidence). In any event, the absence of state-

[8] The same reasoning applies to arguments made by Abbott and Dey that the United States had a duty to preserve emails and other documents in the possession, custody, and control of State Medicaid agencies. The United States has never had possession, custody, or control of such documents, had no knowledge or warning of any destruction, and therefore had no duty to preserve them.

level claims data will only result in lower damages than what otherwise would have been calculated. *See* Henderson Decl., Exhibit 13, Declaration of Mark G. Duggan, Ph.D., in Support of the United States' Motion for Partial Summary Judgment and in Opposition to Defendants' Motions for Partial Summary Judgment, ¶ 82 ("My findings indicate that the total value of the damages is actually substantially higher when I use the claims data collected directly from the states compared to when I extrapolated using the SDUD and SMRF/MAX/MSIS claims data. The fact that I did not have complete state Medicaid claims data collected directly from the states for the entire time period considered for these states reduced rather than increased the total value of the damages."). Roxane has had every opportunity to attempt to demonstrate actual prejudice, but has not done so. Roxane could have obtained and analyzed (and still can) state-level claims data that Dr. Duggan has not used (such data clearly exists), and used that to attempt to attack Dr. Duggan's extrapolations and show that Roxane's defense is thereby prejudiced. But Roxane has not done this, and has not otherwise explained how its defense is prejudiced by the lack of data. If there is any prejudice resulting from the absence of state-level claims data, it is prejudice to the United States, not to any defendant.

III. CONCLUSION

For the foregoing reasons, the Roxane Defendants' Motion For a Finding of Spoliation and For Sanctions should be denied.

DATED: August 21, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

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Dated: August 21, 2009